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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,049	12/01/2003	Erning Xia	P03373	2954

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EXAMINER	
CHORBAJI, MONZER R	
ART UNIT	PAPER NUMBER
1797	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/725,049	XIA ET AL.	
	Examiner	Art Unit	
	MONZER R. CHORBAJI	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5,6,10,13 and 14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5,6,10,13 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This final action is in response to the amendment received on 9/24/07

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1, 5, and 10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claim 1, Applicant added the limitation that the quaternized ammonium cationic polysaccharides are sole preservatives. However, the specification teaches in examples 1-4 that all the compositions in the provided tables include EDTA in addition to quaternized ammonium cationic polysaccharides. EDTA (ethylenediaminetetraacetic acid) is a known preservative. For example, see Ellis et al ('730); column 7, lines 46-48). The same applies to claims 5 and 10.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all 1, 5obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1, 3, 5-6, and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ellis et al (U.S.P.N. 4,436,730).

Regarding claim 1, Ellis discloses an aqueous ophthalmic solution (col.1, lines 61-67 and col.5, lines 9-15) that includes one quarternized ammonium cationic polysaccharides (col.10, lines 26-41 and examples VI-VII. JR-125; JR-400; JR-30M. See Applicant's specification [0019]) in an amount effective for solution preservation (example VI and col.2, lines 54-62). Ellis teaches the use of a buffer system (col.7, lines 55-57) and a chelating agent (col.7, lines 47-49). As to the limitation that the one or more quaternized ammonium cationic polysaccharides being the sole preservatives, Ellis teaches that the preservative benzylalkonium chloride can be used (col.7, lines 46-49) component of the disclosed composition, but it is optional. As such, one of ordinary skill in the art would recognize that in certain embodiments the composition would include an aqueous ophthalmic solution along with quarternized ammonium cationic polysaccharides as the sole source of preservatives (as the instant amended claim

recites) while in other embodiments additional additives such as buffers and chelating agents are added to the quarternized ammonium cationic polysaccharides. It would have been obvious to eliminate the benzylalkonium chloride from the solution to avoid any sensitivity to such a preservative. The elimination of an element with the consequent loss of its function is not an unobvious modification of the prior art.

Regarding claims 3 and 6, Ellis employs variations of polyquaternium 10 (example IV).

Regarding claim 5, Ellis discloses a method for producing a composition where quaternized ammonium cationic polysaccharides (example IV) is combined in amount effective (examples V-VII) for solution preservation (col.2, lines 54-62). As to the limitation that the one or more quaternized ammonium cationic polysaccharides being the sole preservatives, Ellis teaches that the component preservative can be used (col.7, lines 46-49) and is not a required component of the disclosed composition. As such one of ordinary skill in the art would recognize that in certain embodiments the composition would include an aqueous ophthalmic solution along with quarternized ammonium cationic polysaccharides as the sole source of preservatives (as the instant amended claim recites) while in other embodiments additional additives such as buffers and chelating agents are added to the quarternized ammonium cationic polysaccharides. It would have been obvious to eliminate the benzylalkonium chloride from the solution to avoid any sensitivity to such a preservative. The elimination of an element with the consequent loss of its function is not an unobvious modification of the prior art.

Regarding claims 13-14, Ellis discloses a method of using a composition where cationic polysaccharides (example IV) is combined in amount effective (examples V-VII) for solution preservation (col.2, lines 54-62) where surfaces of contact lenses (i.e., medical items) are treated over a time interval so that microbial burden (col.2, lines 59-62 and col.7, lines 59-61) on contact lenses is eliminated.

6. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ellis et al (U.S.P.N. 5,401,327).

Regarding claim 10, Ellis discloses a solution for treatment of contact lenses (col.1, lines 6-8) where the solution includes quarternized ammonium cationic polysaccharides (col.4, lines 63-67 and example 7). Ellis teaches the use of a buffer system col.5, lines 12-15), a chelating agent (col.5, lines 46-48) and a tonicity agent (col.5, lines 10-11). Note that two components are required for this composition. They are polyethylene oxide and a cationic cellulosic polymer as mentioned in column 2, lines 16-39). In addition, Ellis recognizes the relationship between tonicity agents and the osmotic value of the solution (col.5, lines 18-21) and provides value ranges for its value as shown in Table 7 or Table 9. Furthermore, as to the limitation that the quaternized ammonium cationic polysaccharides being the sole preservative, Ellis mentions that when present, the combination of two antibacterial agents for preserving is desirable (col.5, lines 38-43). As such one of ordinary skill in the art would recognize that the combination of the two antibacterial agents is optional and that in certain embodiments this combination is not present and the composition would only include quaternized

ammonium cationic polysaccharides, buffer system, chelating agent, and a tonicity agent.

Response to Arguments

7. Applicant's arguments with respect to claims 1, 3, 5-6, 10, and 13-14 have been considered but are moot in view of the new ground(s) of rejection.

On page 5 of the Remarks section; Applicant argues that the ('730) reference does not teach compositions which have quaternized ammonium cationic polysaccharides as the sole preservatives; that the disclosed quaternized ammonium cationic polysaccharides such as JR polymers are used to provide a thin polyelectrolyte complex on the lens surface; and that ('730) reference suggests that the disclosed quaternized ammonium cationic polysaccharides such as JR polymer cannot provide a preservative effect since the use of preservative is taught.

Ellis ('730) teaches that the component preservative can be used (col.7, lines 46-49) and is not a required component of the disclosed composition. As such one of ordinary skill in the art would recognize that in certain embodiments the composition would include an aqueous ophthalmic solution along with quarternized ammonium cationic polysaccharides as the sole source of preservatives (as the instant amended claim recites) while in other embodiments additional additives such as buffers and chelating agents are added to the quarternized ammonium cationic polysaccharides. In addition, Ellis and the instant claims use the same quarternized ammonium cationic polysaccharides components. Therefore, these components will have preserving properties in the Ellis composition as well.

On pages 5-6 of the Remarks section, Applicant argues that the ('327) reference does not teach a solution that has quaternized ammonium polysaccharides as sole preservative; that the ('327) reference lists preservatives as shown in column 5, lines 29-44; and that the ('327) teaches that the use of quaternized ammonium polysaccharides is to anchor PEO more strongly to the lens surface.

Ellis ('327) mentions that when present, the combination of the two antibacterial agents for preserving purposes is desirable (col.5, lines 38-43). As such one of ordinary skill in the art would recognize that the combination of the two antibacterial agents is optional and that in certain embodiments this combination is not present and the composition would only include quaternized ammonium cationic polysaccharides, buffer system, chelating agent, and a tonicity agent. Applicant refers to column 5, lines 29-44 as a list of preservatives; however, it is a list for antimicrobial agents not a list for preservatives. In addition, Ellis and the instant claims use the same quarternized ammonium cationic polysaccharides components. Therefore, these components will have preserving properties in the Ellis composition as well.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

9. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed

within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R. CHORBAJI whose telephone number is (571)272-1271. The examiner can normally be reached on M-F 9:00-5:30.

11. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797

/M. R. C./